K082881
P1/3

Exhibit#1

510(k) SUMMARY

NOV 24 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland

Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: September, 26, 2008

Contact: Gerhard Frick

2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1)

3. Information for the 510(k) Cleared Device (Predicate Device):

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1), K073198, Microlife Intellectual Property GmbH.
b. Welch Allyn ABPM 6100, K021756, Welch Allyn Inc.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1) is designed to measure systolic and diastolic blood pressure, pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

The device has << AMBULATORY >>, << HOME >> and << CASUAL >> measurement modes and has a medication record function. In addition, the device can be used in connection with your personal computer **(PC)** running the WatchBP O3 software. The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

The <<AMBULATORY>> mode is selected for fully programmable 24-hour patient out-of-office blood pressure measurement. The device automatically takes measurements at fixed intervals programmed by the physician.

The <<HOME>> mode is selected for patient home blood pressure measurement. The patient should carry out two sets of measurements on 7 consecutive working days (or normal week days). Then the patient returns to the physician's office with the subject device for an evaluation of their home blood pressure measurement data.

The <<CASUAL>> mode is selected to function like a regular blood pressure monitor – single measurements are automatically stored and can be reviewed by the physician at a later date.

5. Intended Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device can be used in connection with your personal computer **(PC)** running the WatchBP O3 software .The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The modified device model WatchBP O3 (BP3MZ1-1) and the predicate device model WatchBP Home (BP3MX1-1) use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically, deflation rate is controlled by one factory set exhaust valve and the deflation pressures are transferred via tubing to one sensor.

The major differences between the two models are the additional features such as an AMBULATORY measurement mode and medication record function. However, the differences do not affect the accuracy and normal use of this device.

AMBULATORY measurement mode is similar with what is used in predicate device Welch Allyn ABPM 6100, with 510(k) cleared number K021756.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1) in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

a. Reliability Test - Storage test
b. Reliability Test - Operating test
c. Reliability Test - Vibration test
d. Reliability Test - Drop test
e. Reliability Test - Life test
f. EMC Test
g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP10: 2002 "National Standard for Manual, Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The WatchBP O3 (BP3MZ1-1) met all relevant requirements of this standard, as applicable to our modified device.

The WatchBP O3 (BP3MZ1-1) is, from a technical point of view, identical to the predicate device, Model WatchBP Home (BP3MX1-1). Moreover, the measurement algorithm and its program codes of the WatchBP O3 (BP3MZ1-1) remain unchanged. The fundamental scientific technology of the modified WatchBP O3 (BP3MZ1-1) device is the same as the predicate WatchBP Home (BP3MX1-1) device. Therefore the performance of the WatchBP O3 (BP3MZ1-1) in terms of blood pressure measurement would be identical with performance of the predicate WatchBP Home (BP3MX1-1) device. Repeat clinical testing in accordance with the standard ANSI/AAMI SP10 for the subject WatchBP O3 (BP3MZ1-1) device is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". In addition, since our device requires the use of off-the-shelf software to operate the PC-link function, we adhered to the FDA September 1999 document "Guidance for Off-The-Shelf Software Use in Medical Devices".

10. Conclusions:

We have demonstrated that there are no significant differences between the Microlife Upper Arm Automatic Digital Blood Pressure Monitor Model WatchBP O3 (BP3MZ1-1) and the predicate devices, Model WatchBP Home (BP3MX1-1) and the Welch Allyn ABPN (6100), in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 2008

Microlife Intellectual Property GMBH
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K082881
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP 03 (BP3MZ1-1)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 26, 2008
Received: September 29, 2008

Dear Ms. Goldstein-Falk:

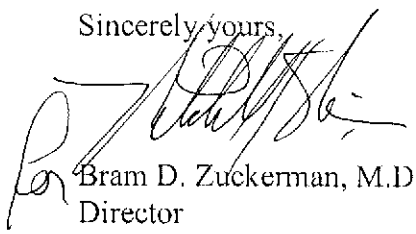
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082881

Exhibit#B

Indications for Use

510(k) Number (if known): K082881

Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1)

Indications For Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3MZ1-1) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device can be used in connection with your personal computer (PC) running the WatchBP O3 software .The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bzackerman

(Division Sign-Off) 11/24/05
Division of Cardiovascular Devices

510(k) Number K082881